European Federation of Pharmaceutical Industries and Associations

ICH

Overview of ICH and industry support to implementation of ICH guidelines by CFDA

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2018 China/Eu Pharmaceutical Industry Forum

Overview of Presentation

- Overview of ICH
- China in the ICH
- Challenges and Opportunities

Overview of ICH

- The ICH Association is now known as the "International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)."
- Unique harmonisation initiative for regulators and pharmaceutical industry
- Originally founded in 1990
- Reformed as a non-profit legal entity under Swiss Law on October 23, 2015

Overview of ICH

Purpose

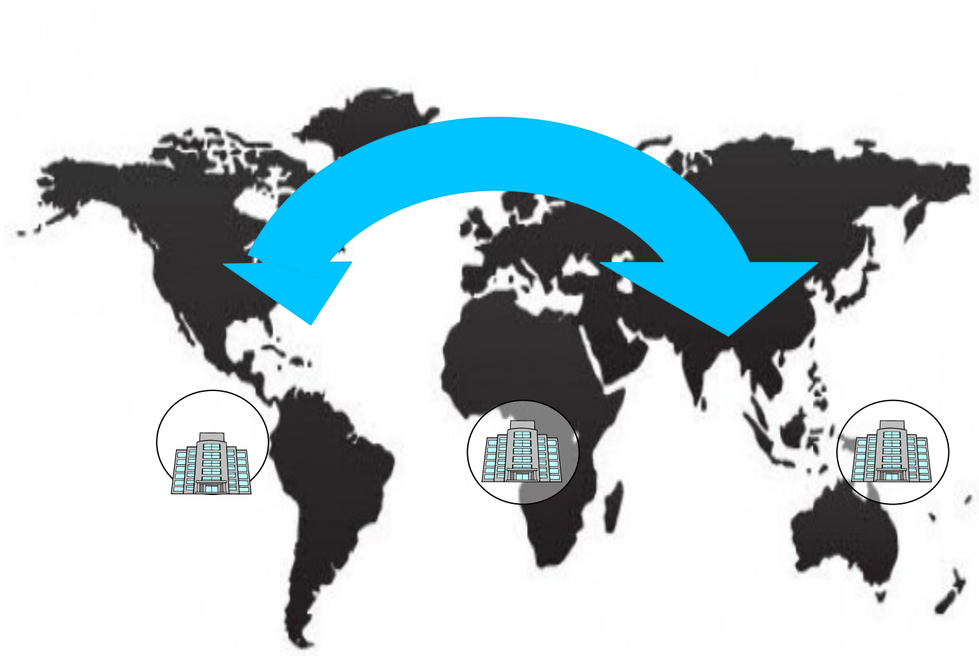
- Promotion of public health through **international harmonisation** that contributes to:
  - Prevention of unnecessary duplication of clinical trial and post market clinical evaluations
  - Development and manufacturing of new medicines
  - Registration and supervision of new medicines
  - Reduction of unnecessary animal testing without compromising safety and effectiveness

Accomplished through **Technical Guidelines** that are implemented by regulatory authorities.

Overview of ICH

ICH Successes

GCP (Good Clinical Practice)

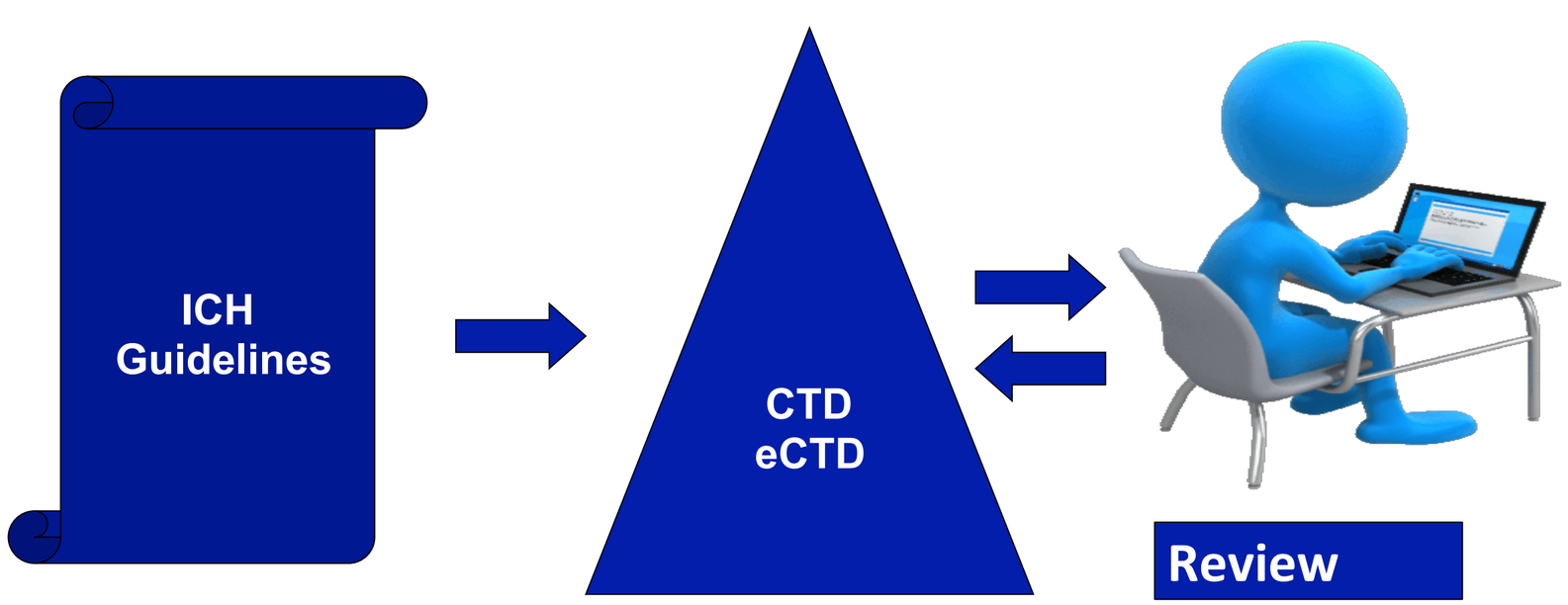


Clinical trials **conducted in one ICH region can be utilised in other ICH regions** by setting the common standards on science and ethics.

Overview of ICH

ICH Successes

CTD/eCTD (Common Technical Document)



CTD brings together all Quality, Safety and Efficacy information in a common, harmonised format, accepted by regulators in all ICH regions. It has revolutionised regulatory review processes for regulators and industry

Overview of ICH

ICH Successes

MedDRA (Medical Dictionary for Regulatory Activities)

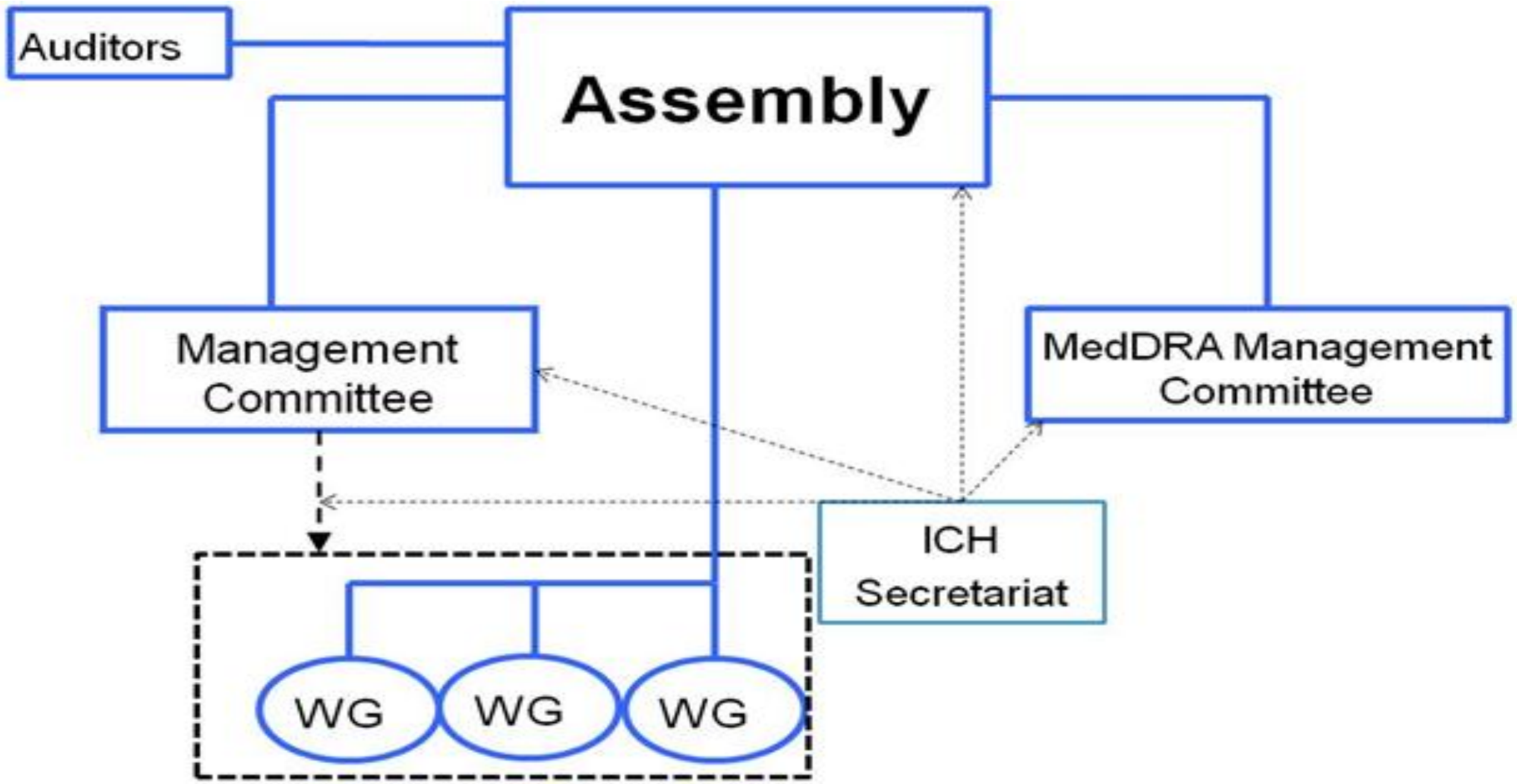
- Highly specific, standardised medical terminology developed by ICH to facilitate sharing of regulatory information
- It is used for registration, documentation and safety monitoring of medical products both before and after marketing authorisation

Keys to ICH Success

- Involves expertise from both regulaty authorities and industry
- Science-based, consensus driven
- Clear and effectively managed process with efficient Secretariat
- Close collaboration with parties with comparable regulatory and technical capability
- Commitment of regulators to implement products of harmonisation
- Common global platform and tolls

Overview of ICH

Structure of the ICH Association



Overview of ICH

Membership in the Assembly – Eligibility Criteria for Regulators

Engagement in the ICH Process:

- Past regular attendance in at least 3 ICH meetings during the previous 2 consecutive years
- Past appointment of experts in WGs

Engagement in the ICH Process:

- Having implemented at least the following ICH guidelines
  - Q1: Stability Testing guidelines
  - Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
  - E6: Good Clinical Practice Guidelines

Overview of ICH

Membership in the Assembly – Eligibility Criteria for Industry

Engagement in the ICH Process:

- Past regular attendance in at least 3 ICH meetings during the previous 2 consecutive years
- Past appointment of experts in WGs

Type of Organisation:

- Be an international pharmaceutical industry organisation representing a global constituency

Impact of ICH Guidelines:

- The organisation and/or its members must be regulated or affected by ICH guidelines

Overview of ICH

ICH Members 16 April 2018

Members:

- **Founding Regulatory Authorities:** EC/EMA, MHLW/PMDA, FDA
- **Founding Industry Associations:** EFPIA, JPMA, PhRMA
- **Standing Regulatory Authorities:** Swissmedic, Health Canada
- **Industry Associations:** IGBA (Generics), WSMI (OTC) and BIO (Biotech)
- **Regulatory Authorities:** MFDS (South Korea), ANVISA (Brazil), CFDA (China) and HSA, Singapore

Overview of ICH

ICH Observers 16 April 2018

- **Standing Observers:** WHO, IFPMA
- **Observers:**
  - *Regional harmonisation initiatives (RHIs):* APEC, ASEAN, EAC, GCC, PANDRA and SADC
  - *Regulatory authorities from* Russia, Australia, Chinese Taipei, India, Mexico, South Africa, Cuba, Kazakhstan and Columbia
  - *International pharmaceutical industry organisations: APIC*
  - *International organisations: IPEC, CIOMS, EDQM, USP, PIC/S and Bill & Melinda Gates Foundation*
- **Ad-hoc observers:** Upon invitation

China in the ICH

ICH guideline implementation by CFDA

- CFDA translated all ICH guidelines to Chinese several years ago. The national industry associations for multinationals, RDPAC helped with the translations

- CFDA started work to implement the medical dictionary MedDRA several years ago. In addition to translations, IT infrastructure needs to be implemented

- Several of the Tier II guidelines, which should be implemented in order to be eligible to be elected as member of the ICH MC requires considerable investment in IT infrastructure, which is time consuming

- The ICH MC has therefore decided only to require full implementation of one Tier II guideline and partial implementation of the rest of the Tier II guidelines

China in the ICH

ICH guideline implementation by CFDA

- Tier II guidelines are the following
  - E2A CLINICAL SAFETY DATA MANAGEMENT: DEFINITIONS AND STANDARDS FOR EXPEDITED REPORTING
  - E2B(R3) CLINICAL SAFETY DATA MANAGEMENT: DATA ELEMENTS FOR TRANSMISSION OF INDIVIDUAL CASE SAFETY REPORTS; IWG IMPLEMENTATION :ELECTRONIC TRANSMISSION OF INDIVIDUAL CASE SAFETY REPORTS
  - E2D: Post-approval Safety Data Management: Definitions and Standards for Expedited Reporting
  - M4 Common Technical Document
  - M1 MedDRA Terminology

Overview of ICH

ICH guideline implementation by CFDA

- CFDA has built up an ICH office, which leads the work with implementation of the ICH guidelines.

- During the last years they have modernized legislation and guidelines in order to implement the basic ICH guidelines and work is ongoing for implementation of other ICH guidelines

- An extensive program with training courses on ICH guidelines have started in 2018, with ICH E17 International Multi-center clinical trials, as the first course in January 2018. EFPIA and PhRMA experts have been given input to program and presented at these training courses

China in the ICH

ICH guideline implementation by CFDA

- During the first half of 2018 training courses in the following ICH guidelines are planned in China

* **April 2018**	**M4 Common Technical Documents CTD**
	E2B Clinical Safety Data Mgm: Data Factors for Transmission of Individual Case Safety Reports
	M1 Medical Terminology MedDRA
* **May 2018**	**E2A Clinical Safety Data Management: Definition and Standard of Report**
	E2D Post-Approval Safety Data Management
	E6 Guideline for Good Clinical Practice
	E8 General Considerations of Clinical Trial
	E11 Clinical Trial of Pediatric Population
	E17 International Multi-center Clinical Trial

ICH guideline implementation by CFDA - Challenges and Opportunities*

Challenges/possible room for improvement:

- Short notice re individual training courses, makes it sometimes difficult to find EFPIA and/or EMA experts to make presentations

- We would have saved some days, if it would have been clarified from the beginning that EFPIA should reach out both to European industry **and** regulator experts.

Opportunities:

- The implemention of ICH guidelines will speed up Chinese patients´ access to new medicinal products. It will also facilitate both for domestic and multinational companies to export their products.

- The action we see from CFDA with the ambitious program for fast implementation of ICH guidelines and revision of legislation and guidelines has convinced me that we are now experiencing a real improvement both re time to approval and re quality

ICH - challenges and Opportunities*

Challenges:

- Keep up the efficiency in the work to develop ICH guidelines, when you get more members and observers

- Keep ICH as a scientific association with regulatory authorities and industry associations as members

Opportunities:

- By opening up ICH for new members, DRAs in emerging markets will influence and implement the ICH guidelines. Guidelines will therefore be harmonised worldwide, which will speed up patients´ access to new medicinal products. It will also facilitate both for domestic and multinational companies to export their products.

- ICH will therefore also be relevant for the future, when production and R&D are moving out from Europe and the US

* My views

European Federation of Pharmaceutical Industries and Associations

BACKUP

Author: Pär Tellner, ICH Coordinator and member of ICH MC, EFPIA * **Date:** 16/04/2018 *






2018 China/Eu Pharmaceutical Industry Forum

Process for selection of new topics

1. ICH members submit proposals for new/revised topics using template by **15 December.** At EFPIA, relevant expert working groups e g Technical Development expert gropup for quality topics endorse new topic proposals before submission.
2. Topic proposals are presented by experts to ICH New topics subcommittee in January/February.
3. A shortlist of topics and an assessment summary report are selected by the new topics subcommittee at the ICH interim meeting, which takes place in the period 15 March – 15 April
4. The ICH Management Committee (MC) approves the assessment summary report from the new topics subcommittee 15 April – 1 May.
5. Assessment summary report and proposals for topics are submitted to ICH Assembly one month before Assembly meeting
6. Final decision at ICH Assembly on new topics at the ICH June meeting

New topics for ICH

At the June 2017 meeting in Montreal, ICH decided to initiate two new topics for harmonisation:

- E8 (R1): Revision of General Considerations for Clinical Trials (Topic lead: FDA)
- E11A: Paediatric extrapolation (Topic lead: FDA)

New topics for ICH

Strategic discussion on harmonisation needs

At the June 2017 meeting in Montreal, we had a strategic topic discussion. We then agreed to develop proposals for strategic discussions on:

- Quality
- Generics
- Gene/Cell therapy
- Vaccines

At the ICH meeting in Geneva in November strategic proposals on quality and vaccines were discussed.

A reflection paper on Good Clinical Practice has already been developed. Please see link below.
http://www.ich.org/products/gcp-renovation.html

Steps in the ICH Process for Guideline Development

Step 5	Implementation
Step 4	Adoption of an ICH Harmonised Guideline
Step 3	Regulatory consultation and Discussion
Step 2	a. ICH Parties consensus on Technical Document / b. Draft Guideline adoption by Regulators
Step 1	Consensus building - Technical Document

The ICH Step Process (1)

- *Step 1:*
  - *WG works to prepare a consensus draft of the technical document.*
- *Step2:*
  - ✓ *Step 2a:*
    - *The Assembly is invited to endorse the technical document.*
  - ✓ *Step 2b*:
    - *The ICH Regulatory Members of the Assembly are invited to endorse the draft Guideline.*

Cont.

The ICH Step Process (2)

- *Step 3:*
  - *Public consultation by the ICH Regulatory Members and ICH Secretariat. All comments are considered by the WG.*
  - *Step 3 is finalised once concensus is reached in the WG.*
- *Step 4:*
  - *The Regulatory Members of the Assembly adopt the final document.*
- *Step 5:*
  - *Implementation by the ICH Regulatory Members.*

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Thank you!

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